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EXAMINER

QM41/1026

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PAPER NUMBER ART UNIT 33

3735 MAILED:

10/26/98

This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTIO	N SUMMARY
Responsive to communication(s) filed on 8/10/98	
☐ This action is FINAL.	
Since this application is in condition for allowance except for forma accordance with the practice under Ex parte Quayle, 1935 D.C. 11	
A shortened statutory period for response to this action is set to expire whichever is longer, from the mailing date of this communication. Failuthe application to become abandoned. (35 U.S.C. § 133). Extensions 1.136(a).	re to respond within the period for response will cause
Disposition of Claims	
Claim(s) 2-7, 16, 21, 423-48 Of the above, claim(s) Claim(s) Claim(s) Claim(s) 2-7, 16, 21 4 23-48	
Claim(s)	
Claim(s)	are subject to restriction or election requirement.
Application Papers	
The drawing(s) filed on The proposed drawing correction, filed on The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.	is approved disapproved.
Priority under 35 U.S.C. § 119	
Acknowledgment is made of a claim for foreign priority under 35 U.	S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the p	riority documents have been
received. received in Application No. (Series Code/Serial Number)	
*Certified copies not received:	
Acknowledgment is made of a claim for domestic priority under 35	U.S.C. § 119(e).
Attachment(s)	
☐ Notice of Reference Cited, PTO-892	,
Information Disclosure Statement(s), PTO-1449, Paper No(s).	
Interview Summary, PTO-413	
Notice of Draftperson's Patent Drawing Review, PTO-948	and the second s
Notice of Informal Patent Application, PTO-152	
SEE OFFICE ACTION ON TI	1E FOLLOWING PAGES-
PTOL-326 (Rev. 9/66)	± U.S. GPO: 1996-404-496/405

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 23, 27, and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an adhesively mounted nasal dilator with a resilient member, does not reasonably provide enablement for a nasal dilator not comprising these elements. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 2, 6, 23, 27, and 47 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling for the claims as recited. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In claims 2, 6, 23, and 27, the lack of recitation of adhesive or properly recited engagement means which is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. In claim 47, the resilient member which is critical or essential to the practice of the invention is only inferentially recited.

Claims 2, 6, 23, 26, and 47 are also rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Evidence that these claims fail to correspond in scope with that which Applicant regards as the invention can be found in the original disclosure, where Applicant has stated that the dilator has to be engaged with the nose adhesively and must include a resilient member in order for both restoring forces and dilation forces to be generated

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to actually dilate the nose. This statement indicates that the invention is different from what is defined in these claims because the no such elements are recited as part of the claimed invention.

Claims 2, 6, 23, 27, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

The omitted elements are the adhesive engagement means and the resilient member.

Claim rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01.

The omitted structural cooperative relationships are those between an adhesive for mounting the dilator on the nose and the resilient member which generates the dilation and restoring forces.

Claims 2-7, 16, 21, and 23-48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 16, and 21, and the claims dependent thereon, do not make sense, and accordingly their scope is unclear. The last two lines of claim 23 do not make sense. Are words missing here? Claim 16 does not make sense in the last paragraph. What is Applicant trying to say by reciting "exposed surfaces". Further, "said flexible strip of material", and "said resilient member" lack proper antecedent basis because such is only inferentially recited. The scope of claim 16 is hard to determine due to the awkward language used. In line 3 of claim 16, "having" seems to be used where

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"comprising" should have been, because "having" connotes multiple elements, i.e. a truss, end surfaces, and a separate flexible strip. This connotation is not supported by the original disclosure. The lack of proper punctuation, i.e. commas, between individual recitations also leads to confusion as to the scope. See claim 16, line 4. There should be a comma or other grammatical or punctuation separator between "material" and "which". All of the claims contain these problems and should be carefully reviewed and amended. As written, all of Applicant's recitations tend to run together.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action: 10

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 21, 32, 33, and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by Spanish patent # 289561 (hereinafter referred to as '561).

Contrast figures 1C and 2C with figure 3 for the planar vs. bent conditions. It is noted that the "restoring forces" limitation is inherently met by a spring. Clear anticipation is withheld due to the 35 USC 112, second paragraph found above.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

25 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

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ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2, 4-7, 16, 23, and 27 are rejected under 35 U.S.C. § 103 as being unpatentable over 10 the Spanish patent ('561).

> As pointed out by Applicant in his 8/10/98 response, '561 teaches Applicant's device as recited in claim 2 with the exception of placing the resilient member on the external surface of the truss, i.e., not between the truss and the nose when worn. Applicant, however, concludes that this is a patentable distinction. The Examiner disagrees. The '561 patent teaches that nasal dilation occurs due to the restoring force of spring 1 puling the nasal cartilage open due to the adhesive holding the spring on the nose, OR due to the adhesion of the spring 1 to a truss 2 which is itself adhesively mounted to the nose. The placement of the spring on either the skin-side of the truss or the outer side of the truss is irrelevant because the same dilation forces are generated. Claims 23, 34, and 37 are also taught by '561 with one exception - plural resilient members vs. a single resilient member. See In re Harza, 124 USPQ 378 (CCPA 1960); St. Regis Paper Co., v. Benis Co., Inc., 193 USPW 8, 11 (7th Cir. 1977). In these cases, it was held that the mere duplication of an element and it's function was a common engineering expedient, and hence, would have been obvious to one of ordinary skill in the art. In

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the instant situation, the replacement of a single resilient member with a spring force "x" with multiple resilient members with a cumulative spring force of "x", would also have been obvious to one of ordinary skill in the art as the mere substitution of functional equivalents. As best as understood, claim 16 is apparently taught by '561 with the exception of the truss being made of plastic. The substitution of one known elastic material for another readily available in the market would have been obvious to one of ordinary skill in the art as a simple economic design choice. Claims 32, 39-43 and 48 fall under the same grounds of rejection. Claims 35 and 38 which in some way recite the adhesive void feature, are taught by '561 due to the placement of the resilient member which inherently provides an adhesive void. Given that '561 teaches on page 5, paragraph 4, that the nasal bandage can be packaged with the adhesive already on it, it would appear inherent that release liners are present for useability. In any event, it would have been obvious to one of ordinary skill in the art to have so provided the

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Claims 28-31 and 44 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112.

'561 device so as to allow the bandages to be removed from their package and stuck

on the nose just as adhesive bandages sold under the trademark "BAND-AID" are.

Applicant's arguments filed 8/10/1998, have been fully considered but they are not deemed to 20 be persuasive.

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Applicant's arguments directed to the Examiner's mis-interpretation of the '561 reference were valid and the rejections have been reconsidered and re-written in response thereto.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner K. L. Asher at telephone number (703) 308-0858.

Any inquiry of a general nature should be directed to the Group receptionist at (703) 308-0858.

10 Status inquiries are to be handled according to MPEP section 203, and directed to the Group receptionist, not the Examiner.

Inquiries as to Terminal Disclaimer and PCT requirements should be directed to the Group Paralegal, Mr. Andre Robinson, at (703) 308-2104.

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October 21, 1998

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Kimberty L. Asher Primary Examiner